

REMARKS

Claims 1-36 have been canceled, and claims 37-39 have been added.

To simplify matters for the examiner, applicants have split-up the prior Markush group into three independent claims. Applicants believe this amendment merely alters the form of the claims and not the scope of the claimed invention.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. INTERVIEW SUMMARY

Applicants thank Examiners Sharareh and Travers for the courtesy of a personal interview held on September 13, 2004. At the interview, the participants discussed the pending rejections: statutory double patenting, obviousness-type double patenting and anticipation under 35 U.S.C. §102(e).

Regarding the statutory double patenting rejection, the examiner asserted that the phrase “to a subject suffering from epilepsy” in claim 1 of U.S. patent No. 6,589,994 has no limiting effect. According to the examiner, therefore, the claim is not limited to treating epileptics. Applicants presented arguments to the contrary.

Regarding the obviousness-type double patenting rejection, applicants indicated their willingness to file a terminal disclaimer. With respect to the anticipation rejection, the examiner asserted that the “wherein” clause identifying the disorders being treated fails to limit the scope of the claimed method. From this perspective, the examiner construed the pending claims as encompassing the treatment of patients generally with isovaleramide. Again, applicants presented arguments to the contrary.

II. STATUTORY DOUBLE PATENTING

The examiner rejects claim 34 under 35 U.S.C. §101, for alleged double patenting in view of claim 1 of U.S. patent No. 6,589,994 (“the ‘994 patent”). According to the examiner,

Both sets of claims are directed to methods of treating convulsions comprising administering a subject an effective amount of isovaleramide. Since the doses of isovaleramide for both conditions are the same, the scope of both sets of claims are identical. Therefore, a statutory [sic] double patenting is proper.”
Office Action, pg. 2, ¶2.

So stating, the examiner has committed several legal errors. First, the examiner applied the wrong analysis. The test for statutory double patenting is not, as asserted by the examiner, whether “the scope of both sets of claims are identical.” Rather, the test involves determining “whether one of the claims could be literally infringed without literally infringing the other.” *In re Vogel*, 422 F.2d 438, 441 (CCPA 1970).

To apply the correct test, applicants turn to the ‘994 patent. The single claim in the ‘994 patent recites “[a] method for treating convulsions, comprising administering an effective amount of isovaleramide to a subject suffering from epilepsy and at risk of suffering convulsions.” The examiner construed the claim as encompassing “methods of treating convulsions comprising administering a subject an effective amount of isovaleramide.” In advancing this construction, the examiner committed a second legal error. Each and every element of a claim defines the invention. *North Am. Vaccine v. American Cyanamid Co.*, 7 F.3d 1571, 1574 (Fed. Cir. 1993). Thus, the examiner erred legally by omitting the claim element “to a subject suffering from epilepsy and at risk of suffering from convulsions.”

Completing the proper analysis, applicants note that claim 34 of the present application is directed to treating a patient with a prescribed neurological disorder (convulsions) by administering an effective amount of isovaleramide. Thus, the instant claim is directed to treating patients with convulsions, while the claim of the ‘994 patent is limited to treating patients suffering from epilepsy and at risk of suffering from convulsions. Like the situation in *In re Vogel*, the pending claim is broader than that of the claim in the cited patent. *In re Vogel*, 422 F.2d at 442. That is, pending claim 34 could be infringed by many methods which would not infringe the claim of the ‘994 patent.

The rejection is improper, therefore, and should be withdrawn.

III. OBVIOUSNESS-TYPE DOUBLE PATENTING

The examiner rejects claims 33-36 under the judicially created doctrine of obviousness-type double patenting, in view of claim 1 of U.S. patent No. 6,589,994 (“the ‘994 patent”). To expedite prosecution, applicants submit concurrently herewith a terminal disclaimer, which applicants believe obviates the rejection.

IV. REJECTIONS UNDER 35 U.S.C. § 102

The examiner rejects claims 33-36 under 35 U.S.C. §102(e) as allegedly being anticipated by Balandrin (U.S. patent No. 5,506,268). Applicants respectfully traverse the rejection.

To reject claims for anticipation, the examiner must demonstrate that each claim limitation is contained in a single reference. *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). Applicants believe the examiner has failed to satisfy this burden.

Indeed, the examiner focused solely on the respective doses of isovaleramide administered to patients. The examiner cites no evidence that Balandrin even suggests, let alone teaches, a method of treating a patient with a neurological disorder, comprising administering to the patient an effective amount of isovaleramide, wherein the neurological disorder is selected from the group consisting of convulsions, spasticity and headaches.

Nor can the examiner's passing reference to the inherency doctrine alleviate the rejection's shortcomings. According to the Federal Circuit, a limitation is inherent only if it is "necessarily present" and "the natural result flowing from the explicit disclosure of the prior art." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991); *Schering Corp. v. Geneva Pharmaceuticals*, 339 F.3d 1373, 1379 (Fed. Cir. 2003). In the instant case, there is no objective evidence of record that treating patient's with convulsions, spasticity and headaches with an effective amount of isovaleramide naturally flows from or is necessarily present in Balandrin's disclosure. Accordingly, Balandrin's patent cannot anticipate, expressly or inherently, the pending claims. Therefore, the rejection should be withdrawn.

Applicants believe that the present application is now in condition for allowance.
Favorable reconsideration of the application as amended is respectfully requested.

The examiner is invited to contact the undersigned by telephone if it is felt that a
telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date 19 October 2004

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